NDA 18-917/S-020 AUG 22 1999

Wyeth-Ayerst Laboratories
Attention: Ms. Roberta R. Acchione
170 North Radnor-Chester Road
St. David's, PA 19087-5221

Dear Ms. Acchione:

Please refer to your supplemental new drug application dated August 27, 1998 submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sectral (acebutolol) 200 mg Capsules.

We acknowledge receipt of your submission dated July 23, 1999.

This supplemental new drug application provides for final printed labeling revised as follows:

1. Under the **DESCRIPTION** section, the last sentence has been changed from:

   Chemically it is defined as the hydrochloride salt of Butanamide, N-[3-acetyl-4-[2-hydroxy-3-[(1 -methylethyl)amino]propoxy]phenyl] ,(±)-or (±)-3' -Acetyl-4' -[2-hydroxy-3-(isopropylamino)propoxy] butyranilide.

   to:

   Chemically it is defined as the hydrochloride salt of (±)N-[3-Acetyl-4-[2hydroxy-3-[(lmethyethyl)amino]propoxy]phenyl]butanamide.

2. Under the **PRECAUTIONS** section, the following subsection has been added:

   Geriatric Use:

   Clinical studies of Sectral and other reported clinical experience is inadequate to determine whether there are differences in safety or effectiveness between patients above or below age 65. Elderly subjects evidence greater bioavailability of acebutolol (see **CLINICAL PHARMACOLOGY - Pharmacokinetics and** Metabolism), presumably because of age-related reduction in first-pass metabolism and renal function. Therefore, it may be appropriate to start elderly patients at the low end of the dosing range (see **DOSAGE AND ADMINISTRATION- Use in Older Patients).**

We have completed the review of the supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on July 26, 1999. Accordingly, the supplemental applications are approved effective on the date of this letter.

If you have any questions, please contact:

Zelda McDonald
Regulatory Project Manager
(301) 594-5333

Sincerely yours,

Raymond J. Lipicky
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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